REMARKS

For the Examiner's convenience Applicants will now address stated issued and grounds for rejection of the pending claims under the appropriate subheadings.

As a preliminary matter, Applicants request clarification of the contents of paragraphs one and two on Page 2 of the Office Action. In the first paragraph, the Examiner stated that, "Applicant's arguments with respect to claims 2-3 and 8-10 have been considered but are moot in view of the new rejection necessitated by applicant's amendment." No amendment was made by Applicants, however, in the last Reply filed (mailed to the U.S. PTO on June 26, 2006). Further, in the second paragraph on Page 2, the Examiner stated that, "The 103(a) rejection of the prior office action is withdrawn due to applicant's amendment of the claims and addition of two new claims not previously rejected." Again, no claim amendments were made in the last Reply filed (mailed to the U.S. PTO on June 26, 2006).

Claim Amendments

Claim 2 has been amended to recite that the unit dosage form is a tablet. Claims 11-13 are newly added and specify that the polymer of the capsule of claim 8 is: in free base form (Claim 11); a salt or partial salt (Claim 12); and crosslinked using epichlorohydrin (Claim 13). Support for the amendment of Claim 1 can be found at Page 14, line 8 of the Specification. Support for newly added Claims 11-13 can be found in, for example, in Claims 9, 10 and 3, respectively.

Rejection of Claims 2-3 and 8-10 Under For Obviousness-Type Double Patenting

The Examiner rejected Claims 2-3 and 8-10 for Obviousness-Type Double Patenting over: Claims 1-4, 6 and 10-12 of U.S. Patent No. **6,083,497**; Claims 12-17 and 19 of U.S. Patent No. **6,264,938**; and Claims 1-4, 6 and 10-12 of U.S. Patent No. **6,248,318**. A Terminal Disclaimer in accordance with the requirements of 37 C.F.R. § 1.321 (c) over these commonly owned patents and the required Statement under 37 C.F.R. § 3.73(b) are being filed concurrently. As such, the rejection is obviated.

Rejection of Claims 2-3 and 8-10 Under 35 U.S.C. § 103(a)

The Examiner rejected Claims 2-3 and 8-10 under 35 U.S.C. § 103(a) as being unpatentable over Keim (U.S. Patent No. 3,700,623). In particular, the Examiner stated that although Keim does not teach that the described resins can be used in a pharmaceutical composition, one of skill in the art would recognize the resins as suitable for a pharmaceutical composition because: the resins are water-soluble; water is a pharmaceutically acceptable carrier; and the resins can be neutralized by acids. Applicants disagree with the Examiner's assertions.

Applicants' claims are directed to a pharmaceutical composition comprising a unit dosage form of an effective amount of a polydiallyamine homopolymer, which is free of alklylated amine monomers, and a pharmaceutically acceptable carrier. Each of the two independent claims specify the structure of the unit dosage form (i.e., Claim 2 specifies a tablet and Claim 8 specifies a capsule).

Keim teaches resins which are used as wet strength agents for paper and which also provide dry strength to paper. At Col 3. lines 63-75, Keim teaches that the resins are applied to the paper by tub application or by spraying of an aqueous resin solution having a solids content of 15% or less. Alternatively, this aqueous solution of resin can be added to an aqueous suspension of paper stock before paper sheet formation. There is no teaching or suggestion in Keim that the materials used to provide a paper with superior wet and dry strengths (e.g., wrapping paper) be used to prepare a pharmaceutical composition in a solid unit dosage form.

More specifically, the aqueous resin solution of Keim would not motivate one of ordinary sill in the art to prepare a pharmaceutical composition in the unit dosage form of a tablet or a capsule. In fact, preparation of a solid unit dosage form would be contrary to the teachings of Keim, which require an aqueous resin solution to strengthen paper. In other words, one of ordinary skill in the art would not be motivated to substitute a capsule or tablet for the aqueous resin solution of Keim, because such a form would destroy the ability to apply the resin to paper,

because one cannot spray a tablet or capsule onto paper or dip paper in a tablet. Furthermore, the use of the resin prior to paper formation requires the addition of the aqueous resin solution, not a tablet or capsule, to the paper stock suspension.

In addition, Keim is non-analogous art and the reference is therefore improperly relied upon by the Examiner in rejecting Applicants' claims. More specifically, references within the statutory terms of 35 U.S.C. §102 qualify as prior art for an obviousness determination only when analogous to the claimed invention. *In re Clay*, 966 F.2d, 656, 658 (Fed. Cir. 1992). Two separate tests define the scope of analogous prior art: (1) whether the art is from the same field of endeavor, regardless of the problem addressed and, (2) if the reference is not within the field of the inventor's endeavor, whether the reference still is reasonably pertinent to the particular problem with which the inventor is involved. *In re Deminski*, 796 F.2d 436, 442 (Fed. Cir. 1986). Keim fails both tests.

In the present application, the claimed invention is in the field of pharmaceuticals, whereas Keim is in the field of paper processing. The Examiner asserted that one of ordinary skill in the art would recognize Keim's resin as suitable for pharmaceutical formulation. On the contrary, pharmaceuticals and paper processing are easily recognized as two different fields of endeavor. That Keim and the present invention are in different technical fields is evidenced by the fact that Keim has an international classification of C08f, whereas the present invention has an international classification of A61K (see e.g., the cover pages of U.S. Patent Nos. 6,083,497, 6,264,938 and 6,248,318, over which the present application is being disclaimed). As such, one or ordinary skill in the art of pharmaceuticals would not look to the paper processing art to prepare pharmaceutical compositions, because the fields are vastly different.

Furthermore, the teachings of Keim are not reasonably pertinent to the particular problem with which the inventors were involved. The purpose of Keim is to process paper with superior wet and dry strengths, not to provide a pharmaceutical composition in unit dosage form for treatment of, for example, hypercholesterolemia. One of ordinary skill in the art would not look to the field of paper processing, to solve a problem in the field of pharmaceuticals. As such, Keim is non-analogous art and therefore an improper reference.

Finally, the Examiner's reference to *In re Spada* in the paragraph bridging Pages 11 and 12 of the Office Action is not understood. The pending rejection is based on obviousness of Applicants' claimed invention, not anticipation as the application of *In re Spada* would suggest. In any event, the aqueous resin solution of Keim is not identical to the unit dosage form (i.e., tablet or capsule) of Applicants' claimed invention

Applicants believe all pending claims meet the requirement of 35 U.S.C. 103(a) and are patentable over the teachings of Keim. Reconsideration and withdrawal of the rejection are respectfully requested.

CONCLUSION

In view of the above amendments and remarks, it is believed that all claims are in condition for allowance, and it is respectfully requested that the application be passed to issue. If the Examiner feels that a telephone conference would expedite prosecution of this case, the Examiner is invited to call the undersigned.

Respectfully submitted,

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